



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,168	08/26/2003	Volker Albrecht	BJA319A	4452
7590 03/07/2006				
BOLESH J. SKUTNIK PhD, JD				
515 Shaker Road				
East Longmeadow, MA 01028				
EXAMINER				
KISHORE, GOLLAMUDI S				
ART UNIT		PAPER NUMBER		
1615				

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,168

Applicant(s)

ALBRECHT ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The filing of RCE dated 12-7-05 is acknowledged. Claims included in the prosecution are 1-16. The examiner notes that the claims presented are the same as those presented originally on 8-26-03, which were rejected before. The following is the office action.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

'said porphyrins macrocycle photosensitizer' in claim 4 lacks an antecedent basis in claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai et al (6,074,666).

Desai et al disclose liposomal compositions containing hematoporphyrin, protoporphyrin, deuteroporphyrin and other porphyrins. Dipalmitoylphosphatidylcholine

Art Unit: 1615

is the preferred phospholipid in making the liposomes. The liposomes are either in suspension form or as a lyophilized powder and contain disaccharides or polysaccharides. The compositions further contain ascorbyl palmitate. The concentration of the porphyrins ranges from 0.1 % up to 0.5 % (abstract, col. 3, lines 43-52, col. 7, line 3 through col. 8, line 52 and claims).

5. Claims 1-3 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Madden (5,389,378).

Madden discloses liposomal formulations containing porphyrins. The phospholipids included dipalmitoylphosphatidylcholine and the liposomes are either in a suspended form or as a lyophilized powder and contain mannitol or glucose (abstract, col. 7, line 8 through col. 9, line 62, Examples and claims). The amounts of the sugars (expressed in millimolar quantities) and the amounts of porphyrins (which are expressed in microgram quantities) as evident from the examples fall within the broad ranges claimed.

6. Claims 1, 3-4, 11-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2146525.

GB discloses liposomal formulations containing hematoporphyrin, protoporphyrin, deuteroporphyrin and other porphyrins. The liposomes contain an additional anti-cancer agent (abstract, pages 5-6 and claims).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5-10, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al in view of Madden both cited and discussed above.

What is lacking in DESAI et al is the use of monosaccharides such as glucose or polyols such as mannitol. The use of these sugars would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since MADDEN teaches that dehydration of the liposomes can be done with a variety of sugars including those taught by DESAI et al and monosaccharides such as glucose and polyols such as mannitol.

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al cited and discussed above, further in view of GB 2146525 also cited and discussed above.

What is lacking in Desai et al is the inclusion of an additional beneficial agent. The inclusion of an additional agent would have been obvious to one of ordinary skill in the art to obtain an added benefit since GB shows the encapsulation of an anti-cancer agent in the liposomes is known in the art.

10. Claims 2, 5-10, 12-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2146525 also cited and discussed above, in view of MADDEN

cited and discussed above.

GB as pointed out above discloses liposomal formulations containing hematoporphyrin, protoporphyrin, deuteroporphyrin and other porphyrins. The liposomes contain an additional anti-cancer agent (abstract, pages 5-6 and claims).

What are lacking in GB are the teachings of lyophilizing the liposomes in the presence of sugars or polyols. Although GB teaches the use of phosphatidylcholine, it does not specifically teach that the phosphatidylcholine be dipalmitoylphosphatidylcholine.

Madden as discussed above, discloses liposomal formulations containing porphyrins. The phospholipids included dipalmitoylphosphatidylcholine and the liposomes are either in a suspended form or as a lyophilized powder and contain mannitol or glucose (abstract, col. 7, line 8 through col. 9, line 62, Examples and claims). The amounts of the sugars (expressed in millimolar quantities) and the amounts of porphyrins (which are expressed in microgram quantities) as evident from the examples fall within the broad ranges claimed. According to Madden, the dehydrated liposomes, dehydrated in presence of protective sugars are storage stable and can be stored for extended periods of time (col. 9, lines 31-62).

It would have been obvious to one of ordinary skill in the art to use dipalmitoylphosphatidylcholine as the specific phosphatidylcholine in the liposomes of GB with a reasonable expectation of success since Madden teaches its routine in the liposomes containing porphyrins. It would have been obvious to one of ordinary skill in the art to dehydrate (freeze-dry) the liposomes of GB in the presence of protective

Art Unit: 1615

sugars such as glucose or mannitol since dehydrated liposomes can be are storage stable and can be stored for extended periods of time as taught by Madden.

11. This is a continuation of applicant's earlier Application No. 10/648,168. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

Art Unit: 1615

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK